



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

Information Collection Request Title: The Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment Surveys, OMB No. 0906-0014, Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment Surveys

OMB No. 0906-0014 – Revision

Abstract: The purpose of the Public Health System Assessment Surveys is to inform the Advisory Committee on Heritable Disorders in Newborns and Children (Committee) on states' ability to add newborn screening for particular conditions, including the feasibility, readiness, and overall capacity to screen for a new condition.

The Committee was established under the Public Health Service Act, 42 U.S.C. 217a: Advisory councils or committees, and Title XI § 1111 (42 U.S.C. § 300b-10). The purpose of the Committee is to provide the Secretary with recommendations, advice, and technical information regarding the most appropriate application of technologies, policies, guidelines, and standards for: (a) effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders; and (b) enhancing the ability of state and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders. Specifically, the Committee makes systematic evidence-based recommendations on newborn screening for conditions that have the potential to change the health outcomes for newborns.

The Committee tasks an external workgroup to conduct systematic evidence-based reviews for conditions being considered for addition to the Recommended Uniform Screening Panel, and their corresponding newborn screening test(s), confirmatory test(s), and treatment(s). Reviews also include an analysis of the benefits and harms of newborn screening for a selected condition at a population level and an assessment of state public health newborn screening programs' ability to implement the screening of a new condition.

Need and Proposed Use of the Information: The Committee's Evidence Review Group administers the surveys to collect data from state newborn screening programs in the United States. The surveys have been developed to capture the following: (1) readiness of state public

health newborn screening programs to expand newborn screening to include the target condition, (2) specific requirements of screening for a condition that could hinder or facilitate implementation in each state, and (3) estimated timeframes needed for each state to complete major milestones toward full implementation of newborn screening for the condition.

The following is a summary of proposed changes to the Committee's Public Health System Assessment Surveys:

Proposed changes to the "INITIAL Survey of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment:"

- Survey title:
 - Current title: "INITIAL Survey of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment"
 - Proposed change: (strike "Secretary's") "INITIAL Survey of the Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment"
 - Rationale: Per the charter signed on November 10, 2020, the Advisory Committee on Heritable Disorders in Newborns and Children is the correct name for the Committee.
- Introductory paragraph:
 - Current introductory paragraph: "The purpose of this survey is to inform the Secretary of Health and Human Services Advisory Committee on Heritable Disorders in Newborns and Children (Committee) about states' ability to add newborn screening (NBS) for [condition x] using information gathered from most of the state and territorial NBS programs in the U.S...."
 - Proposed change: (strike "Secretary of Health and Human Services") "The purpose of this survey is to inform the Advisory Committee on Heritable

Disorders in Newborns and Children (Committee) about states' ability to add newborn screening (NBS) for [condition x] using information gathered from most of the state and territorial NBS programs in the U.S....”

- Rationale: Per the charter signed November 10, 2020, the Advisory Committee on Heritable Disorders in Newborns and Children is the correct name of the Committee.
- Instructions for question 3 (grammatical edit):
 - Current instructions: “...The following question asks you to consider, in general, how much the following factors would be an issue in considering adding [condition x] to your NBS panel.”
 - Proposed change: (strike “in” and replace with “when”) “...The following question asks you to consider, in general, how much the following factors would be an issue when considering adding [condition x] to your NBS panel.”
 - Rationale: Change made to correct a grammatical error.

Proposed changes to the “FOLLOW-UP Survey of the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children’s Public Health System Assessment”

- Survey title:
 - Current title: “INITIAL Survey of the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children’s Public Health System Assessment”
 - Proposed change: (strike “Secretary’s”) “INITIAL Survey of the Advisory Committee on Heritable Disorders in Newborns and Children’s Pub.
 - Rationale: Per the charter signed November 10, 2020, the Advisory Committee on Heritable Disorders in Newborns and Children is the correct name of the Committee.
- Question 9 (grammatical edits):

- Current question: “Have you developed a follow up protocol and/or educational materials for [condition x]? If so please describe the steps for short-term follow and how the plan was developed.”
- Proposed change: (insert hyphen in “follow-up” and insert “-up” in the phrase “short-term follow”) “Have you developed a follow-up protocol and/or educational materials for [condition x]? If so, please describe the steps for short-term follow-up and how the plan was developed.
- Rationale: Change made to correct grammatical errors.

The data gathered informs the Committee on the following: (1) feasibility of implementing population-based screening for the target condition, (2) readiness of state newborn screening programs to adopt screening for the condition, (3) gaps or limitations related to the feasibility or readiness of states to screen for a condition, and (4) areas of technical assistance and resources needed to facilitate screening for conditions with low feasibility or readiness.

Likely Respondents: The respondents to the survey will be state and territorial newborn screening programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
INITIAL Survey of the Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment	59 ¹	2 ³	118	10.0	1,180
FOLLOW-UP Survey of the Advisory Committee on Heritable Disorders in Newborns and Children's Public Health System Assessment	30 ²	2 ³	60	2.0	120
Total	89		178		1,300

* It is anticipated that the proposed revisions will not impact the estimated annualized burden hours.

¹ The respondents to the survey will be state and territorial newborn screening programs.

² Up to 30 states and/or territories will be asked to complete a follow-up survey.

³ Up to two conditions may be reviewed per year.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,
Director, Executive Secretariat.

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